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6. 510(k) Summary

6.1 Applicant and Correspondent:

Name:	GlaxoSmithKline Consumer Healthcare
Address:	1500 Littleton Road Parsippany, NJ 07054-3884
Contact Person:	Zinatara A. Manji, M.S., Pharm.D. Director, Regulatory Affairs
Phone:	(973)-889-2100
Date of Preparation:	September 30, 2009

6.2 Manufacturer:

Sperian Protection Armor SAS
Zl de la Gare
22940 Plaintel
France

6.3 Name of Device:

Trade/Proprietary/Model Name:	Actiprotect™ UF N95 Respirator Double Strap, Flat Fold
Common Name:	Filtering Facepiece Respirator
Classification Name:	Filtering Facepiece Respirator for Use by Healthcare Workers (21 CFR 878.4040) Product Code ONT

6.4 Devices to Which New Device is Substantially Equivalent:

Actiprotect™ UF N95 Respirator K081923

6.5 Device Description:

Actiprotect™ UF N95 Respirator is a double strap, flat-fold style filtering facepiece respirator. It consists of multiple layers of non-woven fabric. A filtration layer provides a barrier to particles of various sizes through mechanical entrapment in a tortuous pathway and by surface attraction by electrostatic forces. The outer layer contains a coating to capture and inactivate viruses. The layers of non-woven fabric are ultrasonically sealed together at the outer perimeter. Two synthetic elastic strips are stapled or welded to the edge of the respirator and are used to secure the mask to the user's face.

6.6 Statement of Intended Use:

Actiprotect™ UF N95 Respirator is a single use, disposable respirator coated with Virucoat™ on the outer layer (active ingredient: citric acid, 1.8%, a pH lowering agent) and is not an antiviral drug. Actiprotect kills (inactivates) 99.99% of influenza A viruses (tested against influenza A subtypes H1N1 (including 2009 pandemic strain)) within one minute of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill (inactivation) on the surface of the outer layer of the respirator when tested in vitro against the following influenza viruses (tested against Influenza A subtypes (and strains): H1N1(JPN/35/2007, JPN/36/2007, including 2009 pandemic strain: NYMC X-179A), H2N2 (A2/JP/305/57), H3N2 (Hong Kong 8/68, JPN/12/2007) and including bird flu subtypes: H5N1 (VNH5N1-PR8/CDCRG), H5N9 (Turkey A/Wisc/68, Myna

A/Mass/71), and Influenza B strains (JPN/85/2007, JPN/128/2007, JPN/143/2007)) under tested contact conditions. No clinical studies have been conducted comparing the ability of an uncoated N95 respirator and this coated N95 respirator to protect the wearer from influenza infection. Actiprotect™ is intended for occupational use during seasonal influenza A or an influenza A pandemic. It is intended to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during seasonal influenza A or an influenza A pandemic. Actiprotect™ UF N95 Respirator also helps to protect the wearer from splash and spray of body fluids.

6.7 Summary of the Technological Characteristics:

Actiprotect™ UF N95 Respirator filters at least 95% of particulates and has a coating on its outermost surface to capture and inactivate influenza viruses on contact with the surface. The predicate device is an N95 respirator: Actiprotect™ UF N95 Respirator, Double Strap Flat Fold.

Actiprotect™ UF N95 Respirator has been tested for and passed standardized tests for fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency (BFE), flammability, and breathing resistance.

The materials of construction used in Actiprotect™ UF N95 Respirator are identical to those of the predicate. Therefore the subject device is substantially equivalent to the predicate device. The device as a whole has been demonstrated to be biocompatible by cytotoxicity and human repeated insult patch testing.

6.8 Brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

- Fluid Penetration Resistance - ASTM F1862
- Particulate Filtration Efficiency - NIOSH 42 CFR 84.181
- Bacterial Filtration Efficiency - MIL M36954C, ASTM F2101
- Flammability - 16 CFR 1610
- Breathing Resistance - NIOSH 42 CFR 84.180

6.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

Human Repeated Insult Patch Tests were conducted using samples of the respirator materials held under occlusive patches. There were no adverse reactions reported during the studies. The outcome of these tests revealed no evidence of sensitization or irritation.

6.10 Conclusions drawn from the nonclinical and clinical tests:

Cytotoxicity and human repeated insult patch tests plus a toxicological review of data on the product's ingredients indicates the product is safe for use in the intended application. Bench testing demonstrated the product's efficacy. Actiprotect™ UF N95 Respirator has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 10 2010

Zinatara A. Manji Ph.D.
Director, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare GlaxoSmithKline
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Re: K093161
Trade/Device Name: Actiprotect ™ UF N95 Respirator, Double Strap Flat Fold
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: March 25, 2010
Received: March 26, 2010

Dear Dr. Zinatara A. Manji:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Actiprotect™ UF N95 Respirator, Double Strap Flat Fold

Indications For Use:

Actiprotect™ UF N95 Respirator is a single use, disposable respirator coated with Virucoat™ on the outer layer (active ingredient: citric acid, 1.8%, a pH lowering agent) and is not an antiviral drug. Actiprotect kills (inactivates) 99.99% of influenza A viruses (tested against influenza A subtypes H1N1 (including 2009 pandemic strain)) within one minute of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill (inactivation) on the surface of the outer layer of the respirator when tested in vitro against the following influenza viruses (tested against Influenza A subtypes (and strains): H1N1(JPN/35/2007, JPN/36/2007, including 2009 pandemic strain: NYMC X-179A), H2N2 (A2/JP/305/57), H3N2 (Hong Kong 8/68, JPN/12/2007) and including bird flu subtypes: H5N1 (VNH5N1-PR8/CDCRG), H5N9 (Turkey A/Wisc/68, Myna A/Mass/71), and Influenza B strains (JPN/85/2007, JPN/128/2007, JPN/143/2007)) under tested contact conditions. No clinical studies have been conducted comparing the ability of an uncoated N95 respirator and this coated N95 respirator to protect the wearer from influenza infection. Actiprotect™ is intended for occupational use during seasonal influenza A or an influenza A pandemic. It is intended to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during seasonal influenza A or an influenza A pandemic. Actiprotect™ UF N95 Respirator also helps to protect the wearer from splash and spray of body fluids.

Prescription Use _____ AND/OR Over-The-Counter Use__X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093161